



CB&I
2700 Chandler Avenue, Building C
Las Vegas, NV 89120
Tel: +1 702 795 0515
Fax: +1 702 795 8210
www.CBI.com

November 15, 2013

Dania Zinner
USEPA; Region 8
1595 Wynkoop Street (8EPR-SR)
Denver, CO 80202-1129

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Dear Ms. Zinner:

EPA CONTRACT NUMBER EP-W-10-033
TASK ORDER NUMBER 3019
QA SUPPORT FOR THE LIBBY ASBESTOS SITE

Enclosed please find the Summary Asbestos On-site Audit Report for the on-site audit performed on July 11, 2013 at ESAT Region 8 SPF in Troy, Montana. This report and the accompanying checklist are deliverables under Task 5 of the subject Task Order.

If you have any questions, please feel free to contact me.

Sincerely,

Timothy L. Vonnahme
Audit Group Manager, QATS Program
CB&I Federal Services, LLC
Phone: (702) 895-8729
E-Mail Address: timothy.vonnahme@cbifederaleservices.com

cc: Administrative Contracting Officer (letter only)
Audit Group Files



REPORT
FOR
TASK ORDER NUMBER 2019
QUALITY ASSURANCE SUPPORT FOR THE LIBBY ASBESTOS SITE
SUMMARY ASBESTOS ON-SITE AUDIT REPORT

ESAT Region 8 – Soil Preparation Facility
Troy, Montana

Prepared by:

The Data Auditing Group
Quality Assurance Technical Support Program
CB&I Federal Services, LLC
2700 Chandler Avenue
Las Vegas, Nevada 89120

November 14, 2013

QATS Contract Number: EP-W-10-033

Prepared for:

Dania Zinner
Task Order Manager

Region 8
U.S. Environmental Protection Agency
1595 Wynkoop Street
Denver, CO 80202

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**Libby Action Plan-Specific Soil Preparation Laboratory On-site Audit Checklist
(EPA Only)**

LABORATORY INFORMATION AND AUDIT SCOPE

This report summarizes the findings of an on-site laboratory audit of the Environmental Services Assistance Team (ESAT) Region 8 Soil Preparation Facility (SPF) in Troy, Montana on July 11, 2013. The SPF facility is operated by personnel from the EPA Region 8 ESAT contractor, Techlaw. The audit was conducted in support of United States Environmental Protection Agency (EPA) Region 8 Libby Superfund Site activities. The primary purpose of the audit was to evaluate corrective actions taken by the laboratory to address deficiencies identified from the last on-site audit conducted on August 7, 2012. CB&I Federal Services, LLC Quality Assurance Technical Support (QATS) staff participation in the on-site audit and subsequent preparation of this report was performed under Task 5, Task Order (TO) 2019, QATS Contract EP-W-10-033.

Detailed information regarding the subject laboratory is as follows:

Date of On-site: July 11, 2013

Laboratory: ESAT Region 8 SPF
Third Street
Troy, Montana 59935
(406) 295-9151

ESAT Region 8 Quality Assurance Coordinator: Nikki MacDonald

Audit Team

US EPA: Elizabeth Fagen, Remedial Project Manager,
Superfund, Region 8

CB&I QATS: Michael Lenkauskas, CQA, Senior Auditor

The Audit Team, comprised of EPA Region 8 and CB&I Federal Services, LLC QATS personnel, performed the technical and evidentiary aspects of the on-site audit. The technical and evidentiary parts of the audit involved an evaluation of the corrective actions taken by the laboratory to address the deficiencies identified during the previous on-site audit conducted on August 7, 2012.

The processes evaluated included sample receipt, bulk soil drying, sample sieving and weighing, sample grinding and splitting, and quality assurance/quality control (QA/QC). All pertinent laboratory instrumentation and equipment were inspected for proper maintenance and calibration, and laboratory personnel were interviewed to determine their understanding and adherence to laboratory procedures.

During the course of the audit, the applicable sections of the Libby Action Plan – Specific Soil Preparation Laboratory On-site Checklist were completed by the QATS Audit Team. Sections of the checklist not completed during the audit are indicated with an "NA." The checklist is provided as an attachment to this report (EPA only).

EXECUTIVE SUMMARY

An on-site laboratory audit was performed at the ESAT Region 8 SPF in Troy, Montana on July 11, 2013 in support of EPA Region 8 Libby Superfund Site activities. The SPF is used to prepare soil samples from Libby Superfund Site Operable Units for shipment to fixed laboratories for analysis by Polarized Light Microscopy (PLM). The primary purpose of the audit was to evaluate the corrective actions taken by the laboratory to address the deficiencies identified during the previous on-site audit conducted on August 7, 2012. The areas evaluated included sample receipt, bulk soil drying, sample sieving and weighing, sample grinding and splitting, and quality assurance/quality control (QA/QC).

The corrective actions applied by the laboratory to the ten (10) deficiencies identified in the July 2013 on-site audit were evaluated during the current on-site audit. The Audit Team determined that the laboratory had completely addressed five (50%), partially addressed one (10%), and failed to address four (40%).

Six deficiencies, five of which were repeat or partial repeat deficiencies, were identified during the laboratory evaluation. The one new deficiency and five repeat deficiencies, are summarized below by laboratory area:

Sample Receipt and Tracking – One deficiency was assessed for lack of a final, complete, and signature-approved SOP for sample receiving, login, tracking, shipping and archiving of samples (**partial repeat defect**).

Bulk Soil Drying – Two deficiencies were assessed for failure to calibrate and certify the balance on an annual basis by an outside vendor, and failure to weigh the measure dried samples to the nearest 0.1 gram, as required by the SOP (**repeat defect**).

Sieving of Preparation Samples – One deficiency was assessed for failure weigh the mass of the coarse fraction to the nearest 0.1 gram, as required by the SOP (**repeat defect**).

Fine Sample Grinding and Splitting – Two deficiencies were assessed for failure to weigh the individual fine fraction to the nearest 0.1 gram, as required by the SOP (**repeat defect**), and failure to accurately determine grinding recoveries due to the use of these incorrect sample weighing procedures (**repeat defect**).

The on-site evaluation revealed SPF-Troy facility to have sufficient facilities, equipment, and staff to prepare PLM samples in accordance with the Libby-specific protocols. All staff and management were cooperative and readily answered all questions asked by the Audit Team. However, the on-site audit did reveal concerns with the procedure used to weigh samples and the laboratory quality system. The fact that the sample receipt SOP was not finalized and signature-approved, that written procedures for weighing samples were not being followed, and that 50% of the deficiencies observed in the previous on-site audit were not corrected suggests an ineffective laboratory quality system.

AUDIT FINDINGS

Sample Receipt, Log-in, Storage, and Chain-of-Custody

The evaluation of this area focused on the one deficiency identified from the previous audit, related to development of a controlled SOP. This deficiency has not been completely addressed:

1. Although the procedures used to receive, login, track, ship and archive samples and prepared samples is now available in a draft SOP, this document still requires revision, and has not yet been finalized or signed. The requirement that all processes are performed in accordance with SOPs is described in Section 5.7 of the Site-wide Quality Assurance Reference Document (QARD) for the Libby Asbestos Superfund Site. (Checklist Nos. 1.7.1 and 1.7.2). **(partial repeat deficiency)**

Recommended Corrective Action – Ensure that the current draft procedures are revised as necessary and finalized.

Bulk Soil Drying

The evaluation of this area focused on three deficiencies identified from the previous audit. Only one of these deficiencies have been addressed as described in the section “Corrective Action Applied from the Previous Audit Deficiencies” on page 7 of this report. One new deficiency and one repeat deficiency were identified:

2. The balance used to weigh samples during each stage of the drying, sieving, and grinding processes has not been certified by a qualified outside technician since 4/23/2012. The requirement that the balance be calibrated on an annual basis by a qualified outside technician is described on the certification sticker on the balance, which indicates certification is overdue. (Checklist Nos. 4.2.3 and 14.1)

Recommended Corrective Action – Calibrate all balances by a qualified outside technician on an annual basis.

3. The mass of dried samples are not measured to the nearest 0.1 gram as described in the SOP. Prior to weighing the dried samples, a single disposable aluminum baking tin is weighed and tared, and that tare weight is used to represent all of the disposable baking tins used; however, during the previous on-site audit several tins were weighed and found to weigh between 13.7 and 14.2 grams, a difference of ± 0.5 grams. The requirement to place each individual empty drying pan on the analytical balance and tare the balance to zero prior to pouring the sample into the drying pan is described in Section 12.2.4.4.1 of the Soil Sample Preparation SOP (ISSI-Libby-01, rev. 11). (Checklist Nos. 6.2.5 and 14.1) **(repeat deficiency)**

Recommended Corrective Action – Ensure that sample weights are accurately measured and recorded as specified in the SOP.

Sieving of Preparation Samples

The evaluation of this area focused on the one deficiency from the previous audit, related to the use by the laboratory of an inaccurate weighing procedure. The evaluation revealed that the

following previously-identified deficiency has not been addressed, as described in the laboratory's response:

4. The mass of the coarse fraction is still not measured to the nearest 0.1 grams as described in the SOP. The 4x6 Zip-lock bags used to collect the coarse fraction are not balance-tared prior to use and their weights are therefore included in the weight of the coarse fraction. The bags weigh between 3.8 and 4.2 grams. The requirement to place the clean poly bag on the analytical balance and tare the balance to zero prior to weighing the coarse fraction is described in Section 14.2.2.1.1 of the Soil Sample Preparation SOP (ISSI-Libby-01, rev. 11). (Checklist Nos. 8.1.1.2, 8.1.1.3, and 14.1)
(repeat deficiency)

Recommended Corrective Action – Ensure that the procedure for weighing samples is performed as specified in the SOP.

Fine Sample Grinding and Splitting

The evaluation of this area focused on two deficiencies identified from the previous audit, neither of which have been found to have been addressed. (See "Corrective Action Applied from the Previous Audit Deficiencies" on page 7 of this report.) The two repeat deficiencies are identified below:

5. The mass of each individual fine fraction is not measured to the nearest 0.1 gram as described in the SOP. The 4x6 Zip-lock bags used to collect the fine fractions are not balance-tared prior to use, and their weights are therefore included in the weight of each fine fraction. The bags weigh between 3.8 and 4.2 grams. The requirement to place the clean poly bag on the analytical balance and tare the balance to zero prior to transfer the fine fraction into the poly bag is described in Section 14.2.5.1.1 of the Soil Sample Preparation SOP (ISSI-Libby-01, rev. 11). (Checklist Nos. 8.1.2.1, 9.2.2 and 14.1)
(repeat deficiency)

Recommended Corrective Action – Ensure that the procedure for weighing samples is performed as specified in the SOP.

6. Because the weight of the disposable aluminum tins used during the drying process can vary by as much as ± 0.5 grams and the Zip-lock bags included in the weights of fine ground and coarse samples can weigh as much as 4.2 grams, the grinding recovery criteria of 90% of the material placed in the grinder cannot be determined. The requirement that the net recovery of fine ground material not be less than 90% of the mass of fine material placed into the grinder is described in Section 12.3.2 of the Soil Sample Preparation SOP (ISSI-Libby-01, rev. 11). (Checklist Nos. 9.2.3 and 14.1)
(repeat deficiency)

Recommended Corrective Action – Ensure that samples are weighed in accordance with written procedures to allow for the accurate determination of grinding recoveries.

Quality Assurance/Quality Control (QA/QC)

The evaluation of this area focused on two deficiencies identified from the previous audit, related to inconsistencies in a form and the sample preparation work plan. These deficiencies were found to have been adequately addressed, as described in the section "Corrective Action

Applied from the Previous Audit Deficiencies” on page 7 of this report. No additional form-related deficiencies were observed.

The fact that the sample receipt SOP was not finalized and signature-approved, that actual sample weighing procedures were not in accordance with the soil sample preparation SOP, and that 50% of the defects from the previous on-site audit were not corrected reflect an ineffective quality system.

CORRECTIVE ACTION APPLIED FROM THE PREVIOUS AUDIT FINDINGS

The on-site laboratory evaluation included an assessment of the ten (10) deficiencies identified and reported in the previous on-site audit performed on August 7, 2012. Of those 10 deficiencies, the audit team determined that the laboratory had completely addressed five, for a corrective action rate of 50%. Of the remaining five deficiencies, one was partially addressed, and four were not addressed. The following are the deficiencies identified during the previous on-site audit, the laboratory's verbatim responses to the audit finding comments, and effectiveness checks performed during the current on-site audit.

Facilities

No facility-related deficiencies were identified.

Sample Receipt, Log-in, Storage, and Chain-of-Custody

1. Although the Sample Coordinator has recently documented the procedures used to receive, login, track, ship, and archive samples and prepared samples, the procedures are not controlled or in a standardized SOP format. The written procedures are currently available on many separate draft documents and not within one or more controlled SOPs. The requirement that all processes are performed in accordance with SOPs is described in Section 5.7 of the Site-wide Quality Assurance Reference Document (QARD) for the Libby Asbestos Superfund Site. (Checklist Nos. 1.7.1 and 1.7.2)

Recommended Corrective Action – Ensure that controlled written procedures are available for all sample receiving, login, shipping, tracking, and archive activities.

Laboratory Response (11/16/2012): See Corrective Action Report (CAR) 2012-0030 (Attachment A)

Rather than include these procedures in SOP ISSI-LIBBY-01 (currently under revision), which focuses on the preparation of soil samples for the analysis of asbestos content by an approved laboratory, ESAT will create a new SOP (PLM-03.00) to detail the procedures used to receive, log-in, track, ship, and receive samples and prepared samples at the SPF. This SOP will be complete and ready for implementation prior to the start of the 2013 field season. SOP PLM-03.00 will be reviewed and updated according to the current version of ESAT SOP QAQ-07.00, Guidance for the Preparation, Approval and Implementation of Standard Operating Procedures.

Effectiveness Check (07/22/2013): This deficiency has been partially addressed. The SOP remains in draft form. It needs to be reviewed, completed, and signature-approved.

Bulk Soil Drying

2. Although the analytical balance is properly calibrated with 1, 10, and 100 gram reference weights, the measured weights are not recorded but indicated by a check mark in the balance calibration logbook. The requirements to calibrate the balance before use with S-1 class weights and to record all measurements are described in Section 6.1 of the Soil Sample Preparation SOP (ISSI-Libby-01, Rev. 10). (Checklist Nos. 4.2.2 and 14.1)

Recommended Corrective Action – Ensure that all measured weights made during balance calibration are recorded in the balance calibration logbook.

Laboratory Response (11/16/2012): See CAR 2012-0031 (Attachment B)

SOP ISSI-LIBBY-01 is currently under revision (Revision 11 was submitted to the client for review on 07/27/2012). Section 12.1.1 was revised to say the following: "Before weighing samples, perform the verification check using Class 6 weights (equivalent to Class S-1 weights) and record the results, any required maintenance, and the balance number in the Analytical Balance Verification and Maintenance Logbook." A new Analytical Balance Verification and Maintenance Logbook template is being created by the QA Coordinator for use at the SPF. The new logbook will include space to record all information required by the SOP.

Effectiveness Check (07/22/2013): The deficiency has been adequately addressed.

3. The oven temperatures are maintained at approximately 94°C and not at the 90°C ($\pm 1^\circ\text{C}$) temperature range specified in the SOP. The requirement for the oven temperature to be set at 90°C ($\pm 1^\circ\text{C}$) is described in Section 6.2 of the Soil Sample Preparation SOP (ISSI-Libby-01, Rev. 10). (Checklist Nos. 4.1.2 and 14.1)

Note: The SOP revision log indicated that this requirement was changed to 90°C ($\pm 10^\circ\text{C}$) on 05/14/2007; however, this change is not reflected in the SOP.

Recommended Corrective Action – Ensure that the oven(s) are calibrated to the temperature specified in the SOP.

Laboratory Response (11/16/2012): See CAR 2012-0032 (Attachment C)

SOP ISSI-Libby-01 is currently under revision (when the revision is complete it will be Revision 11). Section 12.2.3 has been revised so that the oven temperatures must be set to 90°C ($\pm 10^\circ\text{C}$).

Effectiveness Check (07/22/2013): The deficiency has been adequately addressed.

4. The mass of dried samples are not always measured to the nearest 0.1 grams as described in the SOP. Prior to weighing the dried samples, a single disposable aluminum baking tin is weighed and tared, and that single tare weight is used to represent all of the disposable baking tins used; however, during the on-site, several tins were weighed and found to weigh between 13.7 and 14.2 grams, a difference of 0.5 grams. The requirement to record the sample mass of each dried sample to the nearest 0.1 grams is described in Section 6.2 of the Soil Sample Preparation SOP (ISSI-Libby-01, Rev. 10). (Checklist Nos. 6.2.5 and 14.1)

Recommended Corrective Action – Ensure that sample weights are measured and recorded as specified in the SOP.

Laboratory Response (11/16/2012): See CAR 2012-0033 (Attachment D)

The SOP is currently under revision (the new revision will be Revision 11). Sections 12.2.4 and 12.2.7 have been revised so that procedures for weighing dried samples accurately represent what SPF personnel are currently doing and are more clearly stated.

Effectiveness Check (07/22/2013): This deficiency has not been addressed.

Division of Archive and Preparation Samples

No findings during the division of archive and preparation sample process were identified.

Sieving of Preparation Samples

5. The mass of the coarse fraction is not measured to the nearest 0.1 grams as described in the SOP. The 4x6 Zip-lock bags used to collect the coarse fraction (which weighs between 3.8 and 4.2 grams) is not weighed prior to use, and their weight is included in the weight of the coarse fraction. The requirement to weigh and record the mass of the coarse fraction to the nearest 0.1 grams is described in Section 8.2 of the Soil Sample Preparation SOP (ISSI-Libby-01, Rev. 10). (Checklist Nos. 8.1.1.2, 8.1.1.3, and 14.1)

Recommended Corrective Action – Ensure that sample weights are measured and recorded as specified in the SOP.

Laboratory Response (11/16/2012): See Section 14.2.2 of SOP ISSI-LIBBY-01, Revision 11 (Attachment E)

Section 8.2 SOP ISSI-LIBBY-01, Rev. 10 states the following: "Pour all material which does not pass through the screen (>1/4 inch) into a new, tared, sample bag. This is the Coarse Fraction. Weigh and record the mass of the coarse fraction to the nearest 0.1 g in the Sample Preparation Log." The procedures followed by SPF personnel include placing the new sample bag on the analytical balance, taring the balance to zero, pouring the sample material that does not pass through the screen into the sample bag, and then recording the weight of the sample to the nearest 0.1 g. The SOP is currently under revision, and Section 14.2.2 has been revised so that these procedures are more clearly stated.

Effectiveness Check (07/22/2013): This deficiency has not been addressed.

Fine Sample Grinding and Splitting

6. The plate grinder calibration is not performed as described in the SOP. A ¼ inch shim is used to perform the daily plate grinder calibration, which is incorrectly verified by weekly sieving (not daily) of material to verify the particle size to be approximately 250 µm, and this calibration is not recorded in laboratory logbooks. The requirements to use 60-mesh (250 µm) and 200-mesh (74 µm) sieves to verify particle size on a daily basis and to record said verification in the Grinder Calibration and Maintenance logbook is described

in Section 9.1 of the Soil Sample Preparation SOP (ISSI-Libby-01, Rev. 10). (Checklist Nos. 4.3.1 and 14.1)

Recommended Corrective Action – Ensure that the plate grinder is calibrated as described in the SOP.

Laboratory Response (11/16/2012): See CAR 2012-0012 (Attachment F) and Section 15.1.2 of SOP ISSI-LIBBY-01, Revision 11 (Attachment G)

ESAT is no longer able to reliably acquire the grinder calibration soil from USGS required in SOP ISSI-LIBBY-01, Rev. 10; therefore, the 60-mesh and 200-mesh sieves were not utilized. The use of 60-mesh and 200-mesh screens was very qualitative and had a wide range of grinder plate widths that would pass the criteria. When the SPF began to run out of the calibration soil, personnel began experimenting with ways to measure the gap between the grinder plates after calibration. They measured the correct (middle most result after screening ground soil) gap after soil calibration to be 16/1000ths of an inch and found a disposable cardboard shim to use in the interim. The PLM analysis lab gives constant feedback on soil particle size. In fact, the PLM group's specifications exceed SOP ISSI-LIBBY-01 – too fine and the asbestos bundles get crushed; too coarse and they have to perform extra grinding by hand. Some samples were ground too fine or too coarse during the initial start-up of the SPF (when there was still soil for calibration), but none after the SPF ran out of soil. During the week of 07/04/12, ESAT performed a study with 1 Kg of the USGS Arvada Soil found by EPA. The study confirmed that the 16/1000th shim used by the SPF was equivalent to the USGS Arvada soil calibration. This study was used as the basis for modification to the SOP.

Currently, a traceable certified micrometer is used as a standard to perform weekly verification checks that the shim being used for calibration is within tolerance (+/-5%). Eventually, shims will fail due to wear, bends, cracks, etc., at which time they will be replaced with a new shim that meets the requirements. The micrometer will be calibrated annually by a third party. Section 15.1.2 of SOP ISSI-LIBBY-01, Rev. 11 was amended with the appropriate information.

Effectiveness Check (07/22/2013): The deficiency has been adequately addressed.

7. The mass of each individual fine fraction is not measured to the nearest 0.1 grams as described in the SOP. The 4x6 Zip-lock bags used to collect the fine fractions (which weigh between 3.8 and 4.2 grams) are not weighed prior to use, and their weight is included in the weight of each fine fraction. The requirement to weigh and record the mass of each fine ground sample is described in Section 10.1 of the Soil Sample Preparation SOP (ISSI-Libby-01, Rev. 10). (Checklist Nos. 8.1.2.1, 9.2.2, and 14.1)

Recommended Corrective Action – Ensure that sample weights are measured and recorded as specified in the SOP.

Laboratory Response (11/16/2012): See Sections 16.1.6 through 16.1.9 of SOP ISSI-LIBBY-01, Revision 11 (Attachment H)

Section 10.1 SOP ISSI-LIBBY-01, Rev. 10 states the following:

“...carefully transfer each [sample portion] into a clean, tared, ziplock sample bag. Weigh each sample portion (FG1 through FG4), and record each mass along with the technician's initials and date in the Sample Preparation Log.”

The procedures followed by SPF personnel include placing the new sample bag on the analytical balance, taring the balance to zero, pouring the fine-ground sample material into the sample bag, and then recording the weight of the sample to the nearest 0.1 g. The SOP is currently under revision, and Sections 16.1.6 through 16.1.9 have been revised so that these procedures are more clearly stated.

Effectiveness Check (07/22/2013): This deficiency has not been addressed.

8. Because the weight of the disposable aluminum tins used during the drying process can vary by as much as ± 0.5 grams and the Zip-lock bags included in the weight of fine ground and coarse samples can weigh as much as 4.2 grams, the grinding recovery criteria of 90% of that placed in the grinder cannot be determined. The requirement that the net recovery of fine ground material not be less than 90% of the mass of fine material placed into the grinder is described in Section 9.3 of the Soil Sample Preparation SOP (ISSI-Libby-01, Rev. 10). (Checklist No. 9.2.3)

Recommended Corrective Action – Ensure sample weights are measured and recorded in a manner which will allow for the determination of the grinding recovery.

Laboratory Response (11/16/2012): See CAR 2012-0033 (Attachment D), as well as the following sections from SOP ISSI-LIBBY-01, Rev. 11: 14.2.2 and 14.2.5 (Attachment E); 16.1.6 through 16.1.9 (Attachment H)

The SOP is currently under revision (the new revision will be Revision 11). The following sections have been revised in order to ensure that sample weights are measured and recorded in a manner which will allow for the determination of the grinding recovery: 12.2.4, 12.2.7, 14.2.2, 14.2.5, and 16.1.6 through 16.1.9.

Effectiveness Check (07/22/2013): This deficiency has not been addressed.

Quality Assurance/Quality Control (QA/QC)

9. The Request for Modification to Laboratory Activities SPF-000001 (effective 06/01/2009) is not consistent with the requirements specified in SOP ISSI-Libby-01 (Rev. 10). Also, a form required by the modification has not been fully implemented. This modification states that individual tare weights of the individual Zip-lock bags used to collect the fine ground portion no longer had to be weighed and that the forms would be modified to reflect their average weight, which was 4 grams (± 0.2 grams). A review of the form by the Audit Team revealed that the form had never been modified to include this average weight. In addition, the most recent data on the actual weight of the bags suggests the standard deviation is actually closer to ± 0.4 grams, which means the requirement to measure the mass of samples to the nearest 0.1 gram cannot be achieved. The requirement to modify the form to include the average weight of the Zip-lock bags is described in Request for Modification to Laboratory Activities SPF-000001. The requirement to weigh and record the mass of each fine ground sample is described in Sections 6.2 and 8.2 of the Soil Sample Preparation SOP (ISSI-Libby-01, Rev. 10). (Checklist No. 14.1)

Recommended Corrective Action – Ensure that Request for Modification to Laboratory Activities SPF-000001 is fully implemented.

Laboratory Response (11/16/2012): See CAR 2012-0034 (Attachment I)

Adjustments have been made to the Sample Preparation bench sheet with each field season, and therefore, SPF personnel were not able to fully implement Request for Modification to Laboratory Activities SPF-000001, nor were the specific procedures in the SOP followed. The SOP is currently under revision (the new revision will be Revision 11). Sections 16.1.6 through 16.1.9 have been revised to reflect the procedures currently followed by the SPF.

Effectiveness Check (07/22/2013): Since it appears that the laboratory modification is not longer applicable, this deficiency has been adequately addressed.

10. The facility description and select procedures described in the available Soil Sample Preparation Work Plan (updated May 14, 2007) is not consistent with the current operations or facility. The following is a partial list of sections identified by the Audit Team that need to be revised to reflect current facility and procedures:

- The facility described in Section 1.3 and depicted in Figure 1.3-1 does not resemble the current facility.
- Section 2.3 states that “FG1” will be sent for analysis, which has recently been changed to randomly select between “FG1,” “FG2,” “FG3,” or “FG4.”
- Section 3.1.2 describes the use of 1000 grams of clean quartz sand for the preparation blank; however, 400 to 600 grams of quartz sand is actually used.
- The grinder calibration procedures described in Section 3.2.1 are not followed.
- Section 3.2.2 states that the oven temperature is calibrated to 90°C (± 10°C); however, the SOP specifies a range of 90°C (±1°C).

The statement that the work plan requirements and procedures will occur at the SPF located in Troy, MT is described in Section 1.0 of the Soil Sample Preparation Work Plan dated May 14, 2007. (Checklist No. 14.1)

Recommended Corrective Action – Ensure that the procedures described in the Soil Sample Preparation Work Plan are consistent with SOP ISSI-Libby-01 and the procedures as currently performed by laboratory personnel.

Laboratory Response (11/16/2012): *The Soil Sample Preparation Work Plan dated May 14, 2007 is actually Attachment F of the Troy Asbestos Property Evaluation (TAPE). At this time, the Work Plan will not be updated. Rather, it was recommended by the client that the Work Plan be retired and SOP ISSI-LIBBY-01, Revision 11 replace the Work Plan as an attachment to the TAPE. All of the findings listed above are being addressed in SOP ISSI-LIBBY-01, Rev. 11, and once the SOP is finalized, all personnel will be advised to refer to the SOP for the proper procedures related to the SPF.*

Effectiveness Check (07/22/2013): This deficiency has been adequately addressed.

Health and Safety

No health and safety-related deficiencies were identified.

CONCLUSIONS

An on-site laboratory audit was performed at the ESAT Region 8 SPF in Troy, Montana on July 11, 2013 in support of EPA Region 8 Libby Superfund Site activities. The SPF is used to prepare soil samples from Libby Superfund Site Operable Units for shipment to fixed laboratories for analysis by Polarized Light Microscopy (PLM). The primary purpose of the audit was to evaluate the corrective actions taken by the laboratory to address the deficiencies identified during the previous on-site audit conducted on August 7, 2012. The areas evaluated included sample receipt, bulk soil drying, sample sieving and weighing, sample grinding and splitting, and quality assurance/quality control (QA/QC).

The Audit Team determined that the laboratory had addressed only five of the 10 deficiencies identified in the previous audit, for a corrective action rate of 50%. Of the remaining five defects, one was partially addressed and four were not addressed.

The on-site audit identified the following deficiencies:

- A final signature-approved SOP for sample receiving, login, tracking, shipping and archiving of samples was not available (**partial repeat defect**).
- The annual calibration and certification of the balance by an outside vendor was overdue.
- Failure to weigh the measure dried samples to the nearest 0.1 gram, as required by the SOP (**repeat defect**).
- Failure to weigh the mass of the coarse fraction to the nearest 0.1 gram, as required by the SOP (**repeat defect**).
- Failure to weigh the individual fine fraction to the nearest 0.1 gram, as required by the SOP (**repeat defect**).
- Failure to accurately determine grinding recoveries due to the use of incorrect sample weighing procedures (**repeat defect**).

The on-site evaluation revealed SPF-Troy facility to have sufficient facilities, equipment, and staff to prepare PLM samples in accordance with the Libby-specific protocols. All staff and management were cooperative and readily answered all questions asked by the Audit Team. However, the on-site audit did reveal concerns with the procedure used to weigh samples and the laboratory quality system. The fact that the sample receipt SOP was not finalized and signature-approved, that written procedures for weighing samples were not being followed, and that 50% of the deficiencies observed in the previous on-site audit were not corrected suggests an ineffective laboratory quality system.

ATTACHMENT

Libby-Specific Asbestos Soil Preparation Laboratory On-site Audit Checklist (EPA Only)

LIBBY ACTION PLAN-SPECIFIC SOIL PREPARATION LABORATORY ON-SITE CHECKLIST

USEPA

Date(s) of On-site: 7/11/2013Laboratory: ESAT Soil Preparation FacilityAddress: 3rd StreetTroy, Montana 59935Telephone: 406-295-9151

Laboratory Personnel Contacted

Name

Title

Andrea WandlerSample CoordinatorTony BrownAssociateCraig MckayLaboratory TechnicianLecia PayneLaboratory TechnicianMichelle CarlsonSample CoordinatorJay JordanLaboratory Technician

Evaluation Team

Name

Title

Elizabeth FagenUSEPA Region 8, Remedial Project ManagerMichael Lenkauskas, CQACB&I Federal Services, LLC (QATS), Senior Auditor

LIBBY ACTION PLAN-SPECIFIC SOIL PREPARATION LABORATORY ON-SITE CHECKLIST

USEPA

Date(s) of On-site: 7/11/2013

1.0 SAMPLE RECEIPT, LOG-IN, STORAGE, & TRACKING		Yes	No	Comments
1.1	Is the sample receiving area adequate, clean, and orderly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.2	Is the sample receiving area secured against unauthorized personnel?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Personnel Interviewed				
<u>Name</u>		<u>Title</u>		<u>Experience</u>
Andrea Wandler		Sample Coordinator		2.5 years
Tony Brown		Associate		4 years
Craig McKay		Laboratory Technician		3.5 years
1.3 Sample Receipt				
1.3.1	Is there a sample custodian and designated alternate responsible for sample receipt and log-in?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.3.2	Are sample shipping containers opened in a HEPA hood (as necessary) to both minimize personal exposure and safeguard against laboratory contamination (explain)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Opened in the exclusion area.
1.3.3	Does the sample custodian verify and record the following when inspecting shipments and reviewing documentation:			
1.3.3.1	Presence and condition of custody seals?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.3.3.2	Presence or absence of Chain-of-Custody (COC) records?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.3.3.3	Presence or absence of air bill sticker(s)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.3.3.4	Sample condition?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.3.3.5	Presence of packaging or packing material which could compromise samples (i.e., vermiculite & polystyrene)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.3.3.6	Problems/discrepancies between samples, documentation, client requests, etc.?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.3.4	Are (COC) records signed and dated at the time of sample receipt?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.3.5	Is a system in place to contact the client in case of absent documentation, or discrepancies between COCs, client requests, etc.?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.3.6	Are subsequent resolutions to problems and discrepancies documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Additional comments:				

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1.0 SAMPLE RECEIPT, LOG-IN, STORAGE, & TRACKING	Yes	No	Comments
1.4 Sample Identification			
1.4.1 Are sample receipt identification logbooks, or a LIMS, used to log-in samples and assign unique laboratory identification numbers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Copies are kept of all COCs associated with samples distributed from the laboratory.
1.4.1.1 Does the logbook or logging system serve as a direct cross-reference between laboratory ID numbers and client ID numbers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.4.2 When samples are split in the laboratory, is there a method in place to assign laboratory numbers to track the sample back to the original sample?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.5 Sample Storage			
1.5.1 Are storage facilities sufficient?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.5.2 Is the sample storage area secured to prevent entry of unauthorized personnel?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.5.3 Does the sample custodian keep storage logbooks?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.5.4 Are samples easy to locate from logbook references?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.6 Sample Tracking			
1.6.1 Is a system in place to keep track of samples and prepared samples entering and leaving the storage, sample preparation, and analysis areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.6.2 Are the retention and/or disposal of unused samples documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
1.7 Standard Operating Procedures (SOPs)			
1.7.1 Do laboratory personnel have access to current project-specific SOPs, laboratory modifications, and other pertinent guidance documents?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Refer to Finding No. 1 of the Audit Report.
1.7.2 Are the applicable laboratory SOPs available and followed by laboratory personnel (list)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Refer to Finding No. 1 of the Audit Report.
<u>Document Title</u>	<u>Control No.</u>	<u>Description</u>	
1.8 Document Control:			
1.8.1 Are all logbooks, notebooks, forms, or other laboratory documents legible, accurate, and complete (list)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<u>Document Title</u>	<u>Description/Comments</u>		
Additional comments			

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2.0 FACILITY	Yes	No	Comments
2.1 Is the facility adequate, clean, and orderly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2.2 Are steps taken to prevent the cross contamination of equipment, supplies, and reagents?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

3.0 PERSONNEL INTERVIEWED		
Name	Title	Experience
Tony Brown	Associate	4 years
Craig McKay	Laboratory Technician	3.5 years
Lecia Payne	Laboratory Technician	1.5 years

4.0 REAGENTS & EQUIPMENT	Yes	No	Comments
4.1 General purpose laboratory oven:			
4.1.1 Checked routinely and recorded in a permanent logbook?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SOP has been revised to state 90°C ± 1°C.
4.1.2 Capable of maintaining a constant temperature between 89-91°C?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4.2 Analytical balances:			
4.2.1 Checked routinely and recorded in a permanent logbook?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Refer to Finding No. 2 of the Audit Report
4.2.2 Capable of measuring in a range of 0.1g to at least 2000g?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4.2.3 Calibrated within the last 12 months by a certified technician?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
4.3 Plate Grinder:			
4.3.1 Checked routinely and recorded in a permanent logbook?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4.3.2 Capable of accepting soil particles of approximately ¼ inch diameter and grinding to produce particles of approximately 250 µm?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4.4 Ventilation Hoods:			
4.4.1 Checked routinely and recorded in a permanent logbook?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4.5 HEPA Vacuum:			
4.5.1 Checked routinely and recorded in a permanent logbook?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4.6 Riffle Splitter:			
4.6.1 With ¾ inch chutes?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4.7 Clean quartz sand:			
4.7.1 For quality control samples and grinder decontamination?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

Additional comments:

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5.0 SOIL STORAGE	Yes	No	Comments
5.1 Are samples grouped into an inventory batch of 50-120 samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5.2 Are samples archived according to inventory batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

6.0 BULK SOIL DRYING	Yes	No	Comments
6.1 Are samples grouped in a drying batch and assigned a drying batch number prior to drying?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
6.1.1 Is a drying blank created for each drying batch prior to loading samples in the oven?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
6.2 Drying Procedure:			
6.2.1 Is the mass of the original samples measured to the nearest 0.1g and recorded on the Sample Drying Log Sheet?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
6.2.2 Are the samples transferred to the respectively labeled drying pans under a negative pressure HEPA filter hood?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
6.2.3 Are the samples dried for 24-48 hours or until completely dry?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Approximately 16 hours.
6.2.4 Are all samples, once cooled, transferred to clean zip top bags (double bagged) under a negative pressure HEPA filter hood?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Aluminum tins with a zip-lock bag.
6.2.5 Is the mass of the dried sample, measured to the nearest 0.1g, recorded on the Sample Drying Log Sheet?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Refer to Finding No. 3 of the Audit Report.
6.3 Decontamination			
6.3.1 Is the inside of the hood, the inside of the oven, and all drying pans decontaminated using a HEPA vacuum and wet wiping after each drying batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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7.0 DIVISION OF ARCHIVE AND PREPARATION SAMPLES	Yes	No	Comments
7.1 Procedure for Sample Division:			
7.1.1 Are the double bagged samples kneaded in the hood to break up any soil clumps?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
7.1.2 If the volume of the processing portion is larger than 200 grams, is that portion split again (Leaving $\frac{3}{4}$ of the sample for archive and $\frac{1}{4}$ for processing)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
7.1.3 Is the archive portion of the sample double bagged in a clean zip top bag and identified?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
7.2 Decontamination:			
7.2.1 Is a HEPA vacuum/compressed air along with brushing/wiping off visible material done to decontaminate the splitter after each sample?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	No brush is used, but cleaning is thorough.
Note: The splitter does not need to be decontaminated following splitting providing the fine ground sample will be immediately split again.			
Additional comments:			

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8.0 PREPARATION SAMPLE SIEVING	Yes	No	Comments
8.1 Sample Sieving Procedure:			
8.1.1 Coarse Fraction:			
8.1.1.1 Is a ¼ inch stainless steel screen with a clean, pre-weighed catch pan used to divide the fractions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
8.1.1.2 Are all materials that do not pass through the screen (>¼ inch) placed in a new, tared sample bag?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Refer to Finding No. 4 of the Audit Report.
8.1.1.3 Is the mass of the coarse fraction, measured to the nearest 0.1g, recorded on the Sample Drying Log Sheet?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Refer to Finding No. 4 of the Audit Report.
8.1.1.4 Is the coarse fraction material double-bagged and identified with the Index ID and "C"?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
8.1.2 Fine Fraction:			
8.1.2.1 Is the mass of the fine fraction, measured to the nearest 0.1g, recorded on the Sample Drying Log Sheet?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Refer to Finding No. 5 of the Audit Report.
Note: If all of the material passes through the screen, record a mass of zero for the coarse fraction.			
8.1.2.2 Is the fine fraction immediately processed? (If no see below)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
8.1.2.3 Is the fine fraction material double-bagged and identified with the Index ID and "F"?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
8.2 Decontamination:			
8.2.1 Is a HEPA vacuum/compressed air along with brushing/wiping off visible material done to decontaminate the sieves, pans, and the pestle after each sample?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Additional comments:			

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9.0 FINE SAMPLE GRINDING	Yes	No	Comments
9.1 Calibration:			
9.1.1 To verify proper particle size and to demonstrate that samples are not over processed, are grinders calibrated daily or after adjustments are made to the plates?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
9.1.2 Is a HEPA vacuum used to decontaminate the hood and processing equipment, following the calibration activities?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
9.2 Grinding Fine Field Samples:			
9.2.1 Is the fine fraction (<1/4 inch) ground to a particle size of approximately 250 µm?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
9.2.2 Are samples masses, measured to the nearest 0.1g and recorded following grinding activities?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Refer to Finding No. 5 of the Audit Report.
9.2.3 Is the net recovery of fine ground material ≥ 90% of the fine fraction material placed into the grinder? Note: If recovery is < 90%, soil grinding must be stopped and the grinder re-adjusted.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Refer to Finding No. 6 of the Audit Report.
9.3 Decontamination:			
9.3.1 Is the grinder decontaminated between samples using a HEPA-vacuum, compressed air, and quartz sand?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

10.0 SPLITTING OF THE FINE GROUND SAMPLE	Yes	No	Comments
10.1 Splitting Procedure for Fine Ground Sample			
10.1.1 Are all splitting activities being performed in the hood?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10.1.2 Is the fine ground soil sample distributed into four approximately equal subsamples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10.1.3 Is each portion of the sample placed in a clean zip top bag and identified with the Index ID and "FG1", "FG2", "FG3", or "FG4"?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
10.2 Decontamination:			
10.2.1 Is a HEPA vacuum and compressed air, along with the brushing/wiping off of visible material, used to decontaminate the splitter after each sample?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Additional comments:			

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11.0 PERFORMANCE EVALUATION (PE) SAMPLES	Yes	No	Comments
11.1 Are PE samples distributed approximately evenly between the different concentration values?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2 Generation and submittal of PE samples:			
11.2.1 Are the contents of the PE bottle, ~ 100g, thoroughly mixed, by inversion and/or rolling?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2.2 Is an aliquot of approximately 20g removed from the PE bottle and packaged as an unprocessed sample?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.2.3 Is the remainder of the PE bottle material, ~ 80g, carried through the full sequence of steps applied to each field sample?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.0 QUALITY CONTROL	Yes	No	Comments
12.1 Preparation Blanks:			
12.1.1 Is the preparation blank comprised of 200-400 grams of clean quartz sand?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.1.2 Is the preparation blank treated identically to a field soil sample?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.1.3 Is at least one preparation blank processed with each drying batch (~ 20 samples)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.1.4 Are preparation blanks assigned a random and unique Index ID and submitted to the laboratory blindly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.2 Grinding Blanks:			
12.2.1 Is the grinding blank comprised of 100-200 grams of clean quartz sand that is passed through the plate grinder?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.2.2 Is one grinding blank prepared daily, for each grinder used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.2.3 Are grinding blanks assigned a random and unique Index ID and submitted to the lab blindly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.3 Performance Evaluation (PE) Samples:			
12.3.1 Is one of each type of PE sample (processed and unprocessed) distributed for each month in which soil processing occurs?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	PESs are now distributed with the PLM inter-laboratory samples.
12.4 Preparation Duplicates:			
12.4.1 Is the preparation duplicate comprised of a field sample divided into two approximately equal portions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.4.2 Is one duplicate sample processed for every 20 field samples prepared?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
12.4.3 Is the preparation duplicate assigned a unique Index ID and submitted to the laboratory blindly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Additional comments:			

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13.0 HEALTH & SAFETY	Yes	No	Comments
13.1 Does the laboratory have a Health & Safety Plan (HSP)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
13.1.1 Is the HSP document available for review?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
13.2 Personal Protective Equipment (PPE):			
13.2.1 Is the appropriate PPE used during sample preparation and decontamination?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
13.3 Ambient Air Monitoring:			
13.3.1 Is the potential for personal exposure and laboratory contamination monitored and minimized through the collection of air and/or wipe samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
13.3.2 What is the frequency at which monitoring samples are collected? _____	--	--	

14.0 STANDARD OPERATING PROCEDURES (SOPS)		Yes	No	Comments
14.1 Are the applicable laboratory SOPs available and followed by laboratory personnel (list)?		<input type="checkbox"/>	<input checked="" type="checkbox"/>	Refer to Finding Nos.3, 4, 5 and 6 of the Audit Report.
<u>Document Title</u>	<u>Control No.</u>	<u>Description</u>		
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15.0 DOCUMENT CONTROL		Yes	No	Comments
15.1 Are all logbooks, notebooks, forms, or other laboratory documents legible, accurate, and complete (list)?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<u>Document Title</u>	<u>Description/Comments</u>			
Additional comments				